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NELSON

ATTY, DOCKET NO

501501 EXAMINER

HM12/0604

FIRST NAMED APPLICANT

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1642

DATE MAILED:

06/04/99

± U.S. GPO: 1996-404-496/40517

This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS

	OFFICE ACTION SUMMARY
	Responsive to communication(s) filed on February 17, 1998
	This action is FINAL.
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 D.C. 11; 453 O.G. 213:
A shortened statutory period for response to this action is set to expire whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will eause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).	
Dis	sposition of Claims
Q.	Claim(s)
	Claim(s) is/are allowed:
	Claim(s)is/are rejected.
Ē	Claim(s)is/are objected to.
<u></u>	Claim(s)are subject to restriction or election requirement.
Ар	pilcation Papers
	See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed onis/are objected to by the Examiner. The proposed drawing correction, filed onis approvedis approvedis approved The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner.
Pri	ority under 35 U.S.C. § 119
	Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
[All Some* None of the CERTIFIED copies of the priority documents have been
	received.
	received in Application No. (Series Code/Serial Number)
٠,	*Certified copies not received:
	Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).
Att	achment(s)
	Notice of Reference Cited, PTO-892
	Information Disclosure Statement(s), PTO-1449, Paper No(s).
	Interview Summary, PTO-413
Image: Control of the con	-Notice of Draftperson's Patent Drawing Review, PTO-948
	Notice of Informal Patent Application, PTO-152
	SEE OFFICE ACTION ON THE FOLLOWING PAGES

1. Claims 31-47 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

- 2. This application contains claims directed to the following patentably distinct species of the claimed invention:
- Therefore, the invention is subject to election of a single disclosed species.

 Claim 31 is generic to a plurality of disclosed patentably distinct species comprising methods of quantifying an analyte whereby the methods are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success whereby the methods are (a) standard addition analysis (claims 32, 36-39) and (b) working curve analysis (claims 33-35, 40-47).
- 4. If Group (b) is elected, Group (b) is further subject to election of a single disclosed species.

Claim 31 is generic to a plurality of disclosed patentably distinct species comprising methods of quantifying an analyte whereby the methods are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success whereby

the methods are (a) the quantifying step comprises a method whereby the working curve analysis is calibrated only at a single point (claims 34, 42 and 43), (b) the quantifying step comprises using working curve analysis whereby standard preparations are analyzed containing known but differing amounts of analyte wherein each has a known amount of IRS and obtaining a mass spectra of each of the standard preparations (claims 33 and 40-41) (c) the quantifying step comprises using multiple internal reference species at varying concentrations to display a working curve directly in a single mass spectrum which also contains the analyte signal (claims 35 and 44-47).

- 5. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.
- 6. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
- 7. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).
- 8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

- 9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.
- 10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
- 11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this

application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar

SUSAN UNGAR D PATENT EXAMINER

May 24, 1999